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**Kroll et al.**

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(45) **Date of Patent: Jun. 29, 2004**

(54) **METHOD AND APPARATUS FOR REDUCED FEEDBACK IN IMPLANTABLE HEARING ASSISTANCE SYSTEMS**

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US 2003/0032856 A1 Feb. 13, 2003

**Related U.S. Application Data**

(62) Division of application No. 09/899,594, filed on Jul. 5, 2001, which is a division of application No. 09/327,345, filed on Jun. 5, 1999, now Pat. No. 6,267,731.

(60) Provisional application No. 60/088,162, filed on Jun. 5, 1998, provisional application No. 60/088,276, filed on Jun. 5, 1998, and provisional application No. 60/088,319, filed on Jun. 5, 1998.

(51) **Int. Cl.**[7] ..... **H04R 25/00**

(52) **U.S. Cl.** ..... **600/25**

(58) **Field of Search** ..... 600/25; 607/55, 607/56, 57; 381/23.1, 312, 317, 318, 322–326, 174, 191

(56) **References Cited**

U.S. PATENT DOCUMENTS

| | | | |
|---|---|---|---|
| 3,594,514 | A | 7/1971 | Wingrove |
| 3,712,962 | A | 1/1973 | Epley |

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

| | | | |
|---|---|---|---|
| DE | 28 34 891 | A1 | 1/1980 |
| DE | 39 18 329 | A1 | 12/1990 |
| DE | 196 18 961 | A1 | 11/1997 |
| DE | 196 38 159 | A1 | 4/1998 |
| EP | 263 254 | A1 | 4/1988 |
| WO | WO 94/17645 | | 8/1994 |

OTHER PUBLICATIONS

"Middle Ear Implant: Implantable Hearing Aids," *Advances in Audiology*, vol. 4, M. Hoke Series Editor, Karger, 1–169 (1988).

(List continued on next page.)

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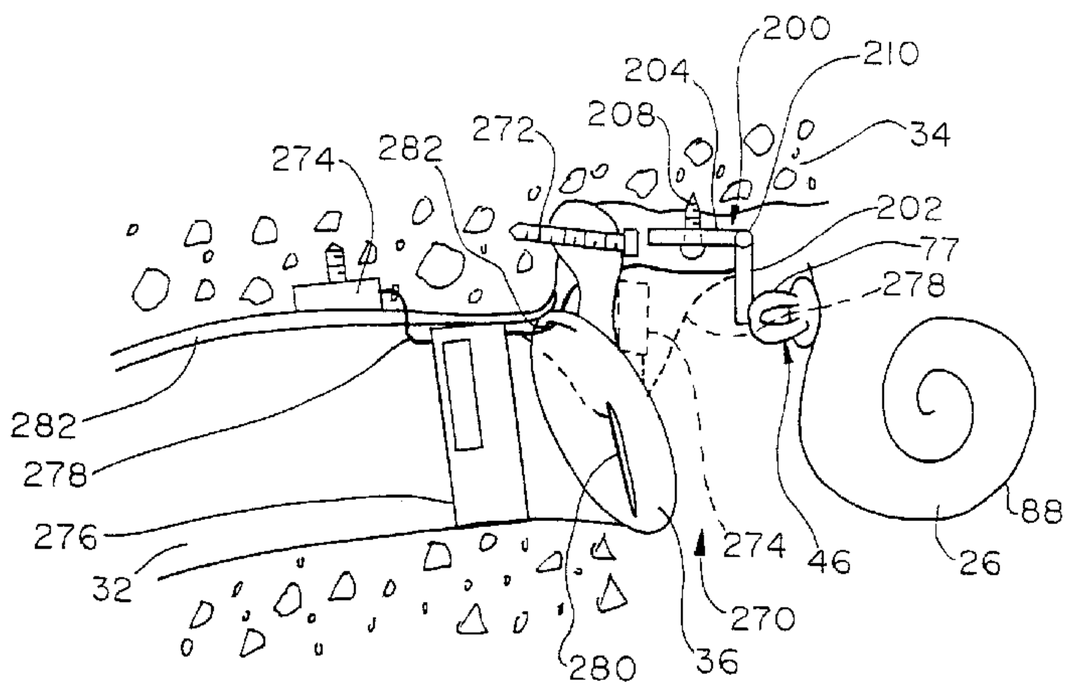
(57) **ABSTRACT**

A method and apparatus assists a hearing impaired person by introducing and maintaining a mechanical feedback barrier between a microphone and a transducer of an implantable hearing assistance system. In this method, mechanical sound vibrations impinging on the person's body habitus are received with an electromechanical device (e.g. microphone) disposed at a body habitus sound reception site. The body habitus sound reception site can be located within the external auditory canal, or external of the external auditory canal either subdermally or external of the scalp. The mechanical sound vibrations are converted with the electromechanical device to an amplified electrical signal. Next, the amplified electrical signal is delivered to the inner ear with a transducer operatively coupled between the electromechanical device and the middle ear or the inner ear. Finally, a mechanical feedback barrier is introduced and maintained between the sound reception site and the transducer to minimize acoustic feedback therebetween. Preferably, this feedback barrier is established by removing, separating, or fixing, or combinations thereof, a portion of the hearing impaired person's ossicular chain (e.g malleus, incus, or stapes).

**11 Claims, 7 Drawing Sheets**



U.S. PATENT DOCUMENTS

| | | | | |
|---|---|---|---|---|
| 3,764,748 | A | | 10/1973 | Branch et al. |
| 3,870,832 | A | | 3/1975 | Fredrickson |
| 3,882,285 | A | | 5/1975 | Nunley et al. |
| 4,150,262 | A | | 4/1979 | Ono |
| 4,169,292 | A | | 10/1979 | Grote |
| 4,466,690 | A | | 8/1984 | Osypka |
| 4,498,461 | A | | 2/1985 | Hakansson |
| 4,601,723 | A | | 7/1986 | McGrew |
| 4,606,329 | A | | 8/1986 | Hough |
| 4,628,907 | A | | 12/1986 | Epley |
| 4,696,287 | A | | 9/1987 | Hortmann et al. |
| 4,729,366 | A | | 3/1988 | Schaefer et al. |
| 4,756,312 | A | | 7/1988 | Epley |
| 4,774,933 | A | | 10/1988 | Hough et al. |
| 4,776,322 | A | | 10/1988 | Hough et al. |
| 4,850,962 | A | | 7/1989 | Schaefer |
| 4,957,478 | A | | 9/1990 | Maniglia |
| 4,969,900 | A | | 11/1990 | Fleischer |
| 4,988,333 | A | | 1/1991 | Engebretson et al. |
| 5,015,224 | A | | 5/1991 | Maniglia |
| 5,015,225 | A | | 5/1991 | Hough et al. |
| 5,085,628 | A | | 2/1992 | Engebretson et al. |
| 5,163,957 | A | | 11/1992 | Sade et al. |
| 5,277,694 | A | | 1/1994 | Leysieffer et al. |
| 5,282,858 | A | | 2/1994 | Bisch et al. |
| 5,338,287 | A | | 8/1994 | Miller et al. |
| 5,370,689 | A | | 12/1994 | Causse |
| 5,411,467 | A | | 5/1995 | Hortmann et al. |
| 5,456,654 | A | | 10/1995 | Ball |
| 5,498,226 | A | | 3/1996 | Lenkauskas |
| 5,554,096 | A | | 9/1996 | Ball |
| 5,558,618 | A | | 9/1996 | Maniglia |
| 5,624,376 | A | | 4/1997 | Ball et al. |
| 5,702,342 | A | | 12/1997 | Metzler et al. |
| 5,776,144 | A | | 7/1998 | Leysieffer et al. |
| 5,788,711 | A | | 8/1998 | Lehner et al. |
| 5,800,336 | A | * | 9/1998 | Ball et al. ..... 600/25 |
| 5,836,863 | A | | 11/1998 | Bushek et al. |
| 5,842,967 | A | | 12/1998 | Kroll |
| 5,881,158 | A | * | 3/1999 | Lesinski et al. ..... 381/174 |
| 5,906,635 | A | | 5/1999 | Maniglia |
| 5,941,814 | A | | 8/1999 | Lehner et al. |
| 5,999,632 | A | | 12/1999 | Leysieffer et al. |
| 6,001,129 | A | | 12/1999 | Bushek et al. |
| 6,050,933 | A | | 4/2000 | Bushek et al. |
| 6,077,215 | A | | 6/2000 | Leysieffer |
| 6,088,619 | A | | 7/2000 | Hein et al. |
| 6,113,531 | A | | 9/2000 | Leysieffer et al. |
| 6,123,660 | A | | 9/2000 | Leysieffer |
| 6,139,488 | A | | 10/2000 | Ball |
| 6,171,229 | B1 | | 1/2001 | Kroll et al. |
| 6,315,710 | B1 | | 11/2001 | Bushek et al. |
| 6,325,755 | B1 | | 12/2001 | Bushek et al. |
| 6,585,637 | B2 | * | 7/2003 | Brillhart et al. ..... 600/25 |

OTHER PUBLICATIONS

Dormer, PhD., K.J., et al., "Selection of Biomaterials for Middle and Inner Ear Implants,": *Otolaryngologic Clinics of North America*, 28:17–27 (1995).

Dumon, M.D., T., et al., "Piezoelectric Middle Ear Implant Preserving the Ossicular Chain," *Otolaryngologic Clinics of North America*, 28:173–188 (1995).

Dumon, T., et al., "Piezoelectric Middle Ear Implant: Experimental Results," Abstract of Paper Presented at International Symposium on Electronic Implants in Otology and Conventional Hearing Aids, Walt Disney World Swan, Abstract #35, (Nov. 11–14, 1996).

Fredrickson, J.M., et al., "Ongoing Investigations into an Implantable Electromagnetic Hearing Aid for Moderate to Severe Sensorineural Hearing Loss,": *Otolaryngological Clinics of North America*, vol., 28, No. 1, 107–121, (Feb. 1995).

Gyo, K., et al., "Stapes Vibration Produced by the Output Transducer of an Implantable Hearing Aid," *Arch Otolaryngol Head Neck Surg.*, vol. 113, 1078–1081 (Oct. 1987).

Ko, Wen H., et al., "Engineering Principles of Mechanical Stimulation of the Middle Ear," *Otolaryngological Clinics of North America*, vol. 28, No. 1, 29–41 (Feb. 1995).

Ko, PhD., W.H., "A Preliminary Study on the Implantable Middle Ear Hearing Aid," *I.E.E.E. 9th Annual Conference on Engineering in Medicine and Biology Society*, (1987).

Kodera, K., et al., Sound Evaluation of Partially Implantable Piezoelectric Middle Ear Implant: Comparative Study of Frequency Responses,: *ENT Journal*, vol. 73, No. 2, 108–111, (Feb. 1994).

Lenkauskas, El, "Totally Implantable Hearing Aid Device," *Transplants and Implants in Otology II*, 371–375 (1991).

Maniglia, A.J., et al., "A Contactless Electromagnetic Implantable Middle Ear Device for Sensorineural Hearing Loss," *ENT Journal*, vol. 73, No. 2, 78–90, (Feb. 1994).

Maniglia, A.J., et al., "Contactless, Semi–Implantable Electromagnetic Hearing Device for the Treatment of Sensorineural Hearing Loss," *Abstract from Paper Presented at International Symposium on Electronic Implants in Otology and Conventional Hearing Aids*, Walt Disney World Swan, Abstract #29, (Nov. 11–14, 1993).

Maniglia, A.J., et al., "Contactless Semi–Implantable Electromagnetic Middle Ear Device for the Treatment of Sensorineural Hearing Loss: Short–Term and Long–Term Animal Experiments,": *Otolaryngologic Clinics of North America*, 28:121–140, (1995).

Maniglia, M.D., A.J., et al., Electromagnetic Implantable Middle Ear Hearing Device of the Ossicular–Stimulating Type: Principles, Designs, and Experiments, *Ann. Otol. Rhinol Laryngol*, 97 (Suppl. P. 136), Part 2, (1988).

Maniglia, M.D., A.J., "Implantable Hearing Devices: State of the Art," *Otolaryngologic Clinics of North America*, 22:175–200, (1989).

Ohno, T., "The Implantable Hearing Aid," *Audecibel*, Fall 1984, Winter 1985 (1984).

Snik, PhD., Ad F.M., et al., "The Bone–Anchored Hearing Aid Compared with Conventional Hearing Aids: Audiologic Results and the Patients' Opinions," *Otolaryngologic Clinics of North America*, 28:73–83 (1995).

Suzuki, J.I., et al., "Implantation of Partially Implantable Middle Ear Implant and the Indication," *Advances in Audiology*, (Karger, Basel), 4:160–166 (1988).

Suzuki, J.I., et al., "Principle, Construction and Indication of the Middle Ear Implant," *Advances in Audiology*, 4:15–21, (1988).

Suzuki, M.D., J.I., et al., "Partially Implantable Piezoelectric Middle Ear Hearing Device: Long–Term Results," *Otolaryngologic Clinics of North America*, 28:99–106 (1995).

Tos; M., et al., "Implantation of Electromagnetic Ossicular Replacement Device," *ENT Journal*, vol. 73, No. 2, 93–103, (Feb. 1994).

Wilpizeski, PhD., C., et al., "A Simple Implantable Electromechanical Middle Ear," Transactions of the Pennsylvania Academy of Ophthalmology and Otolaryngology, 32:41–46, (1979).

Yanagihara, N., et al., "Partially Implantable Hearing Aid using Piezoelectric Ceramic Ossicular Vibrator," Abstract of Paper Presented at International Symposium on Electronic Implants in Otology and Conventional Hearing Aids, Walt Disney World Swan, Abstract #26, (Nov. 11–14, 1993).

Yanagihara, M.D., N., et al., "Partially Implantable Hearing Aid Using Piezoelectric Ceramic Ossicular Vibrator," *Otolaryngologic Clinics of North America*, 28:85–97 (1995).

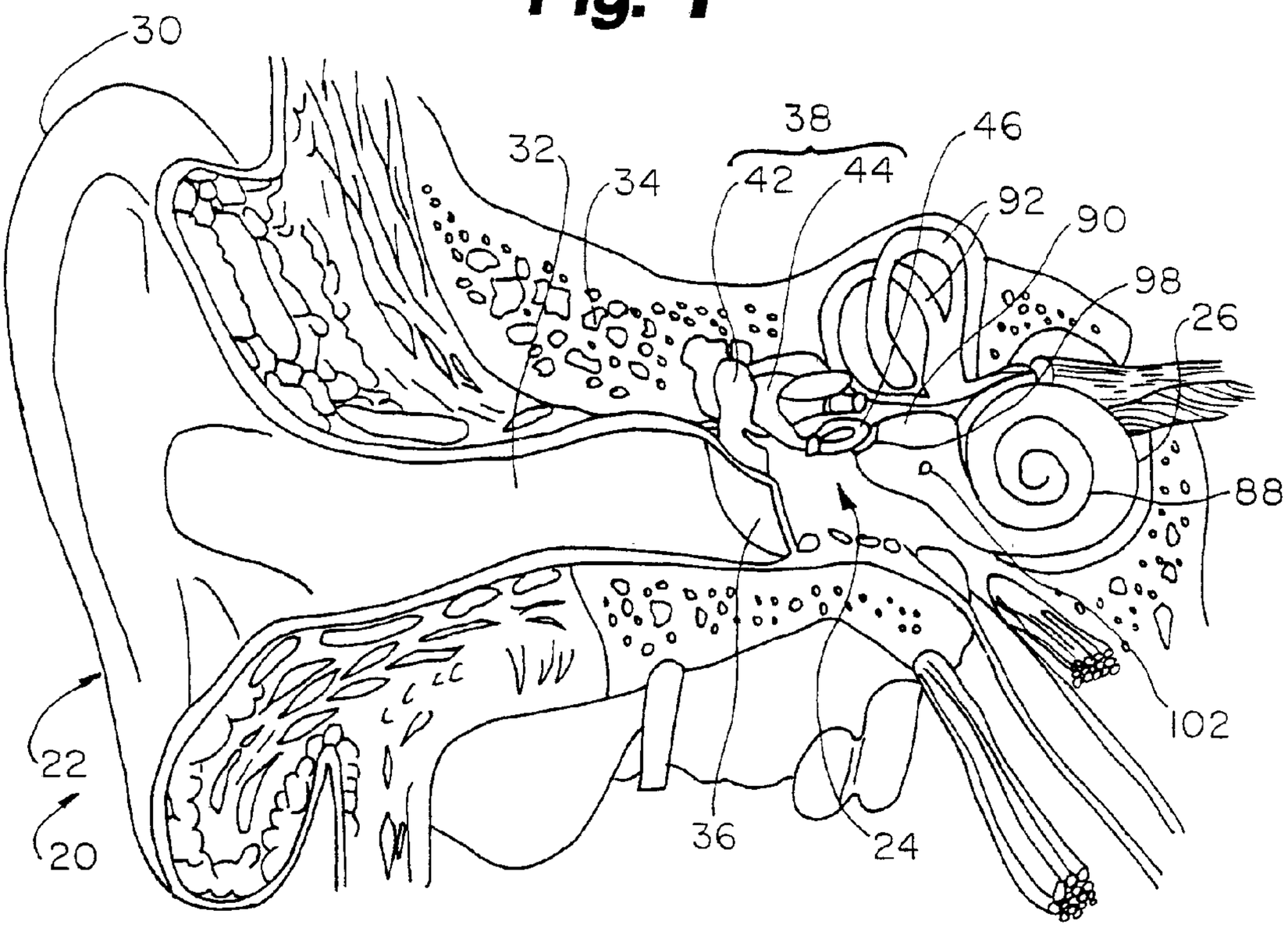
Yanagihara, M.D., N., et al., "Perception of Sound Through Direct Oscillation of the Stapes Using a Piezoelectric Ceramic Bimorph,": *Ann. Otol. Rhinol. Laryngol.*, 92:223–227 (1983).

Yanagihara, M.D., N., et al., "Development of an Implantable Hearing Aid Using a Piezoelectric Vibrator of Bimorph Design: State of the Art," *Otolaryngology Head and Neck Surgery*, 92:706–712 (1984).

Yanagihara, M.D., N., et al., "Implantable Hearing Aid," *Archives of Otolaryngology Head and Neck Surgery*, 113:869–872 (1987).

* cited by examiner-

Fig. 1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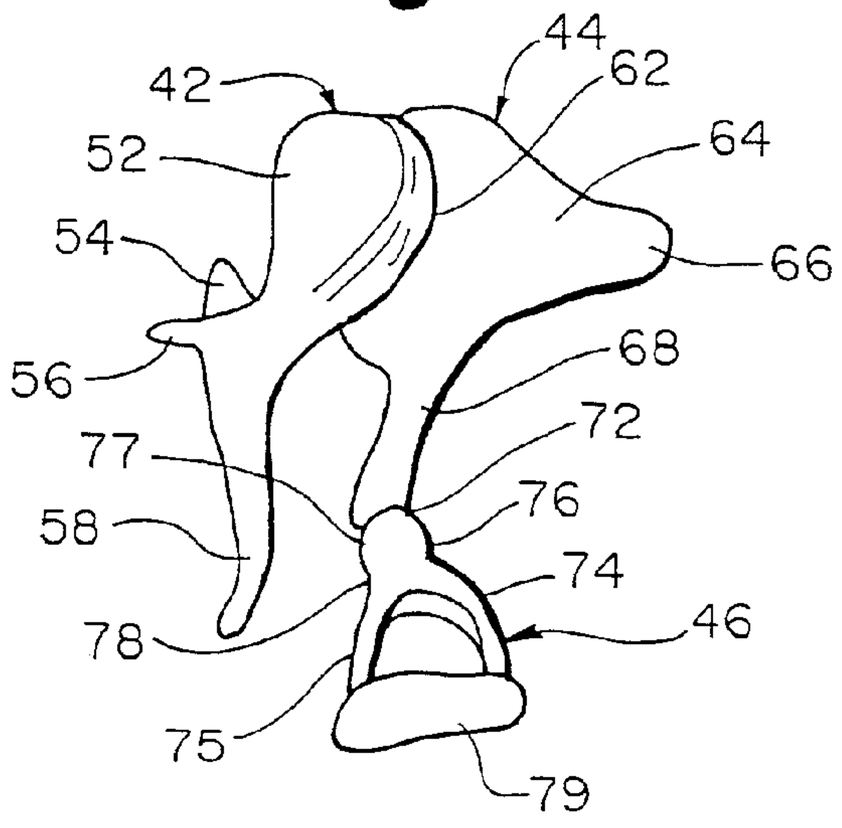
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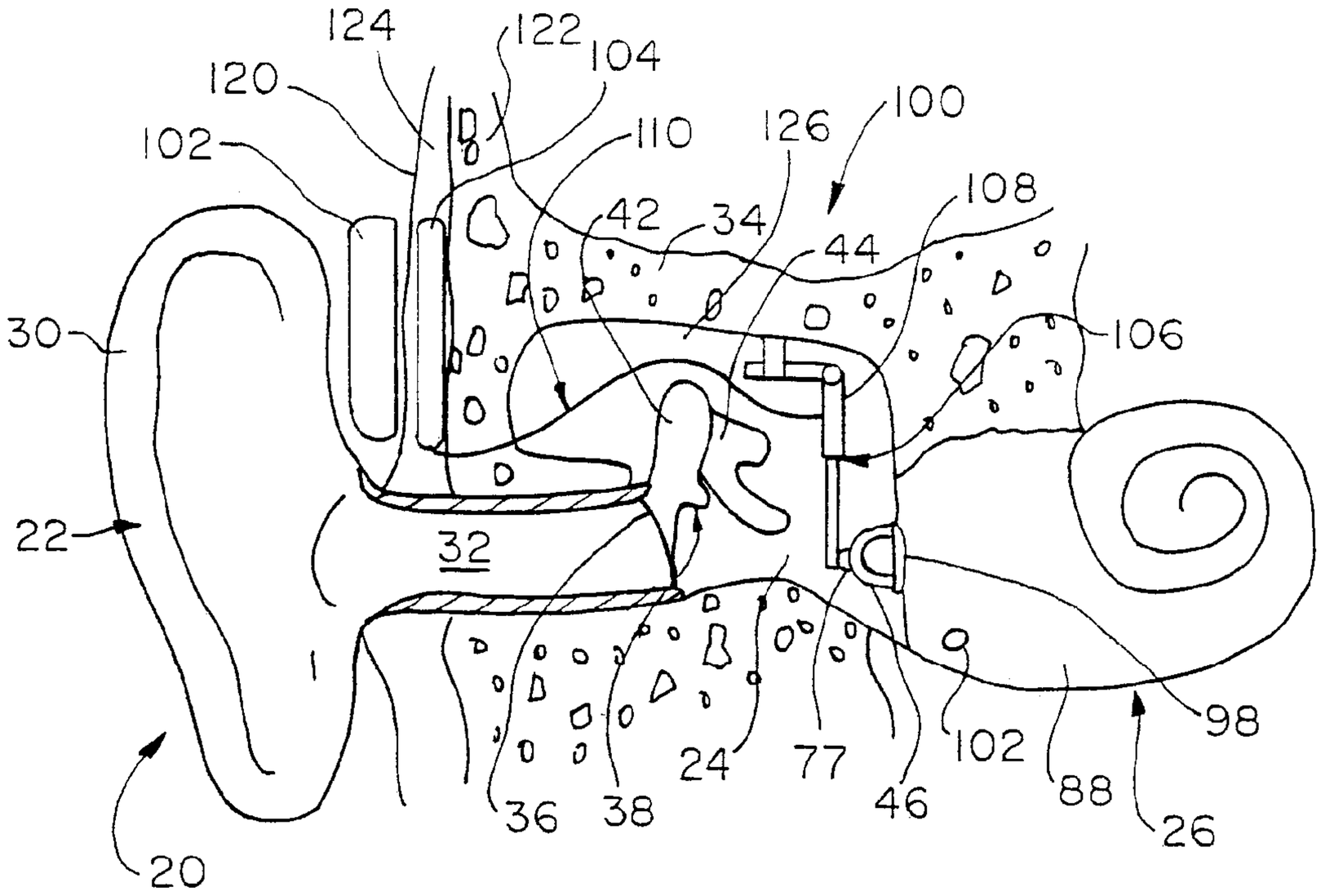
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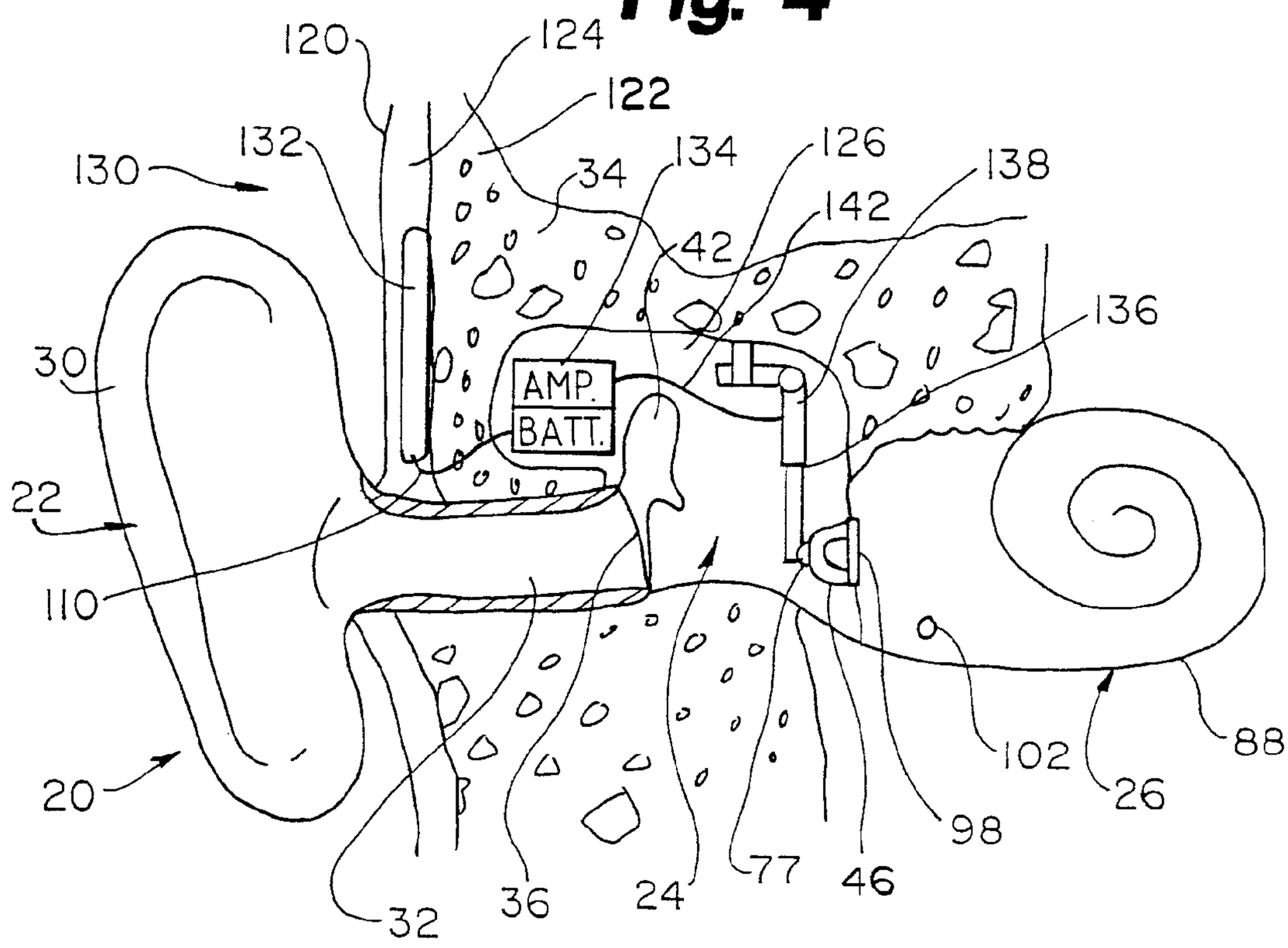
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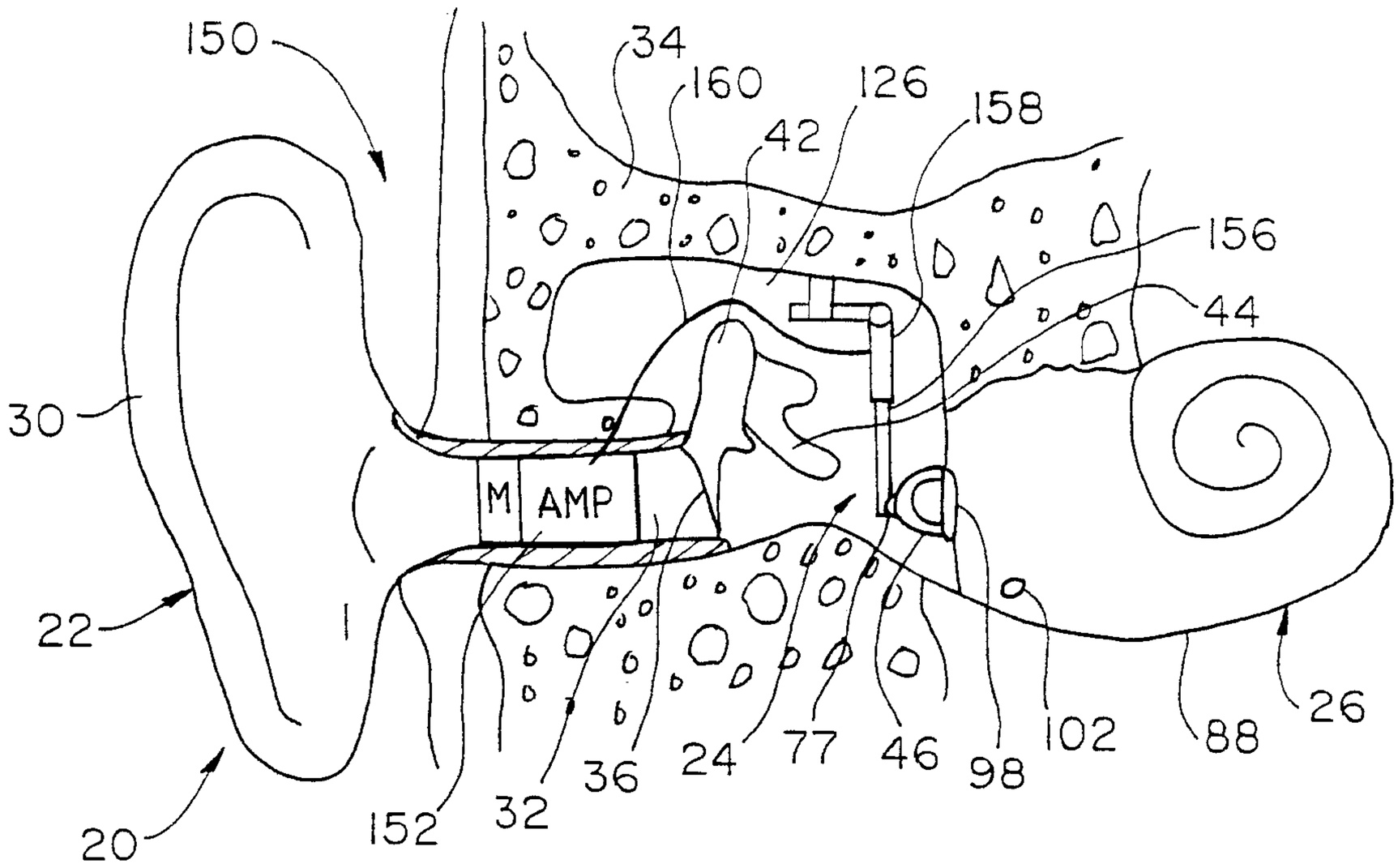
Fig. 5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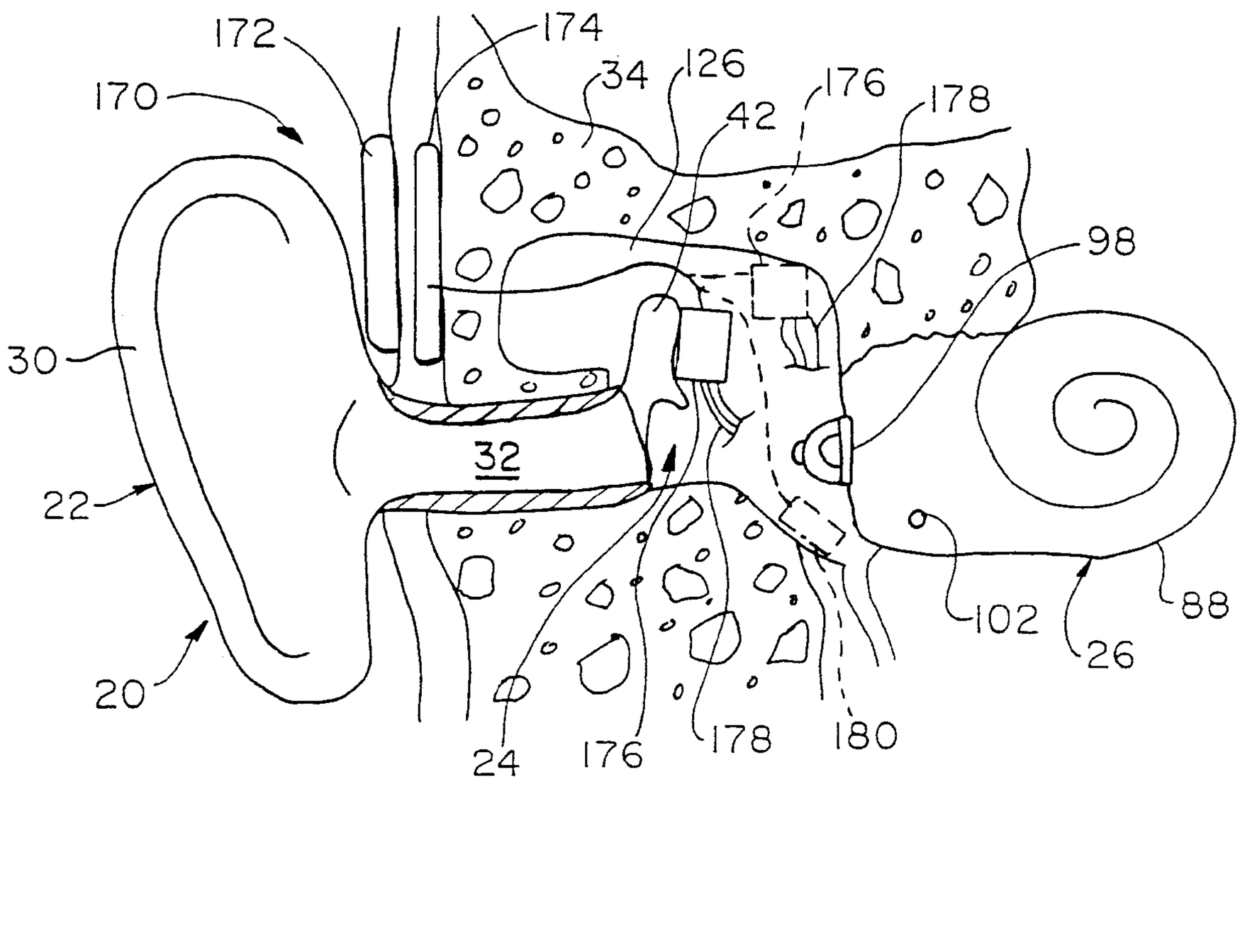
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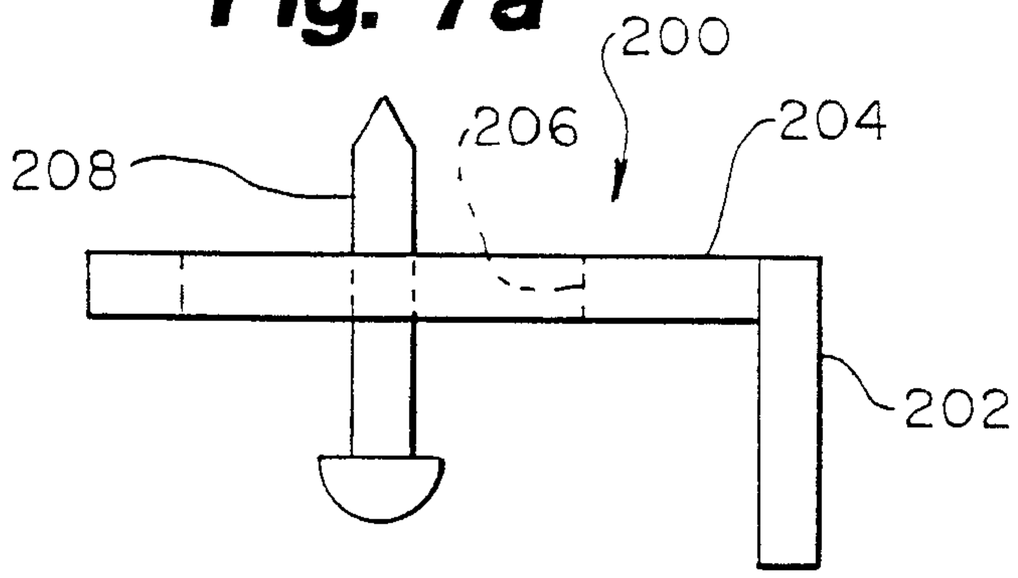
Fig. 7a

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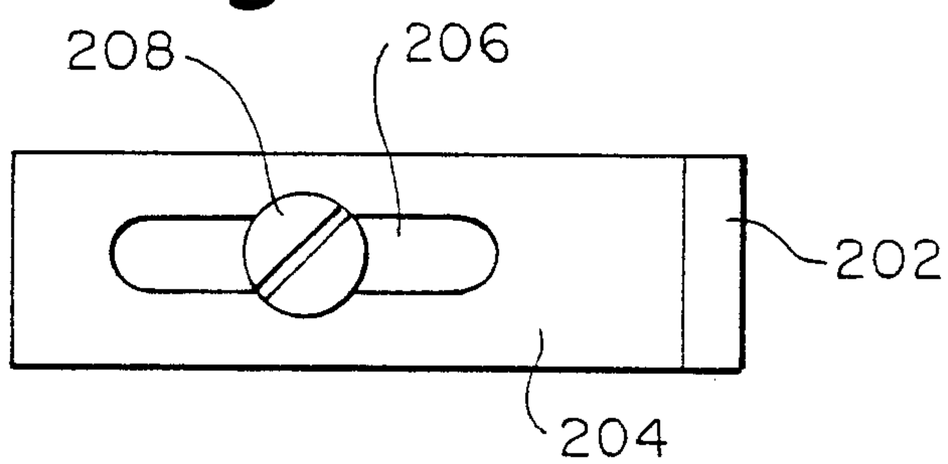


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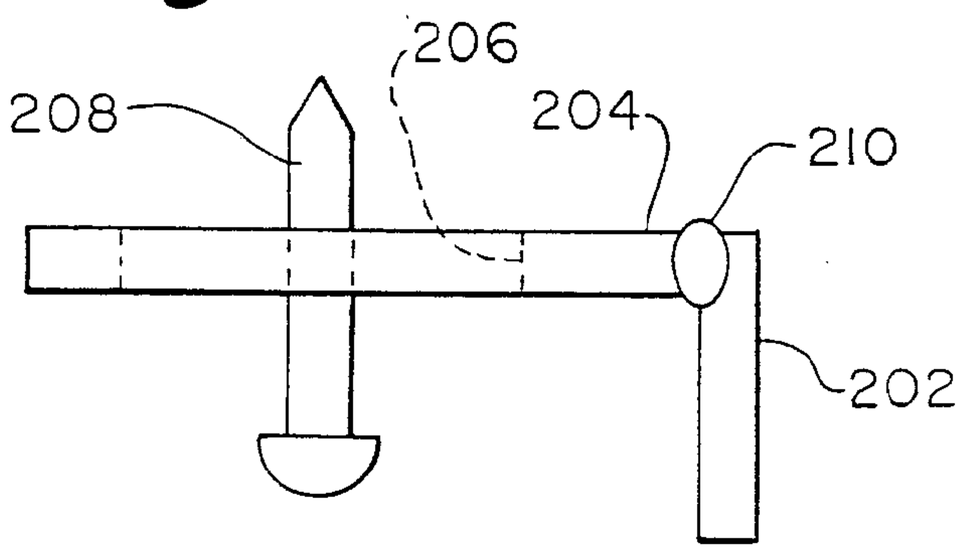

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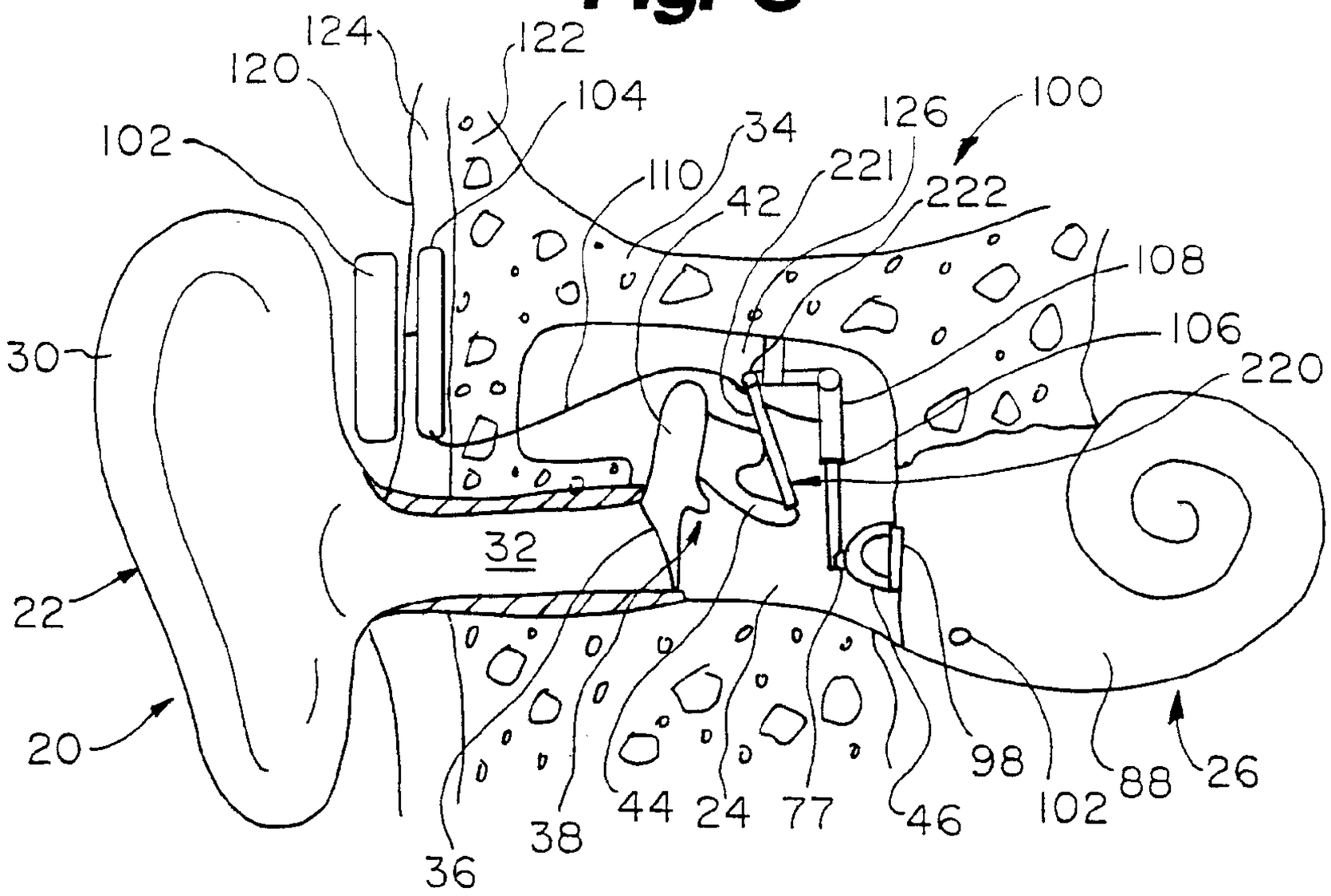
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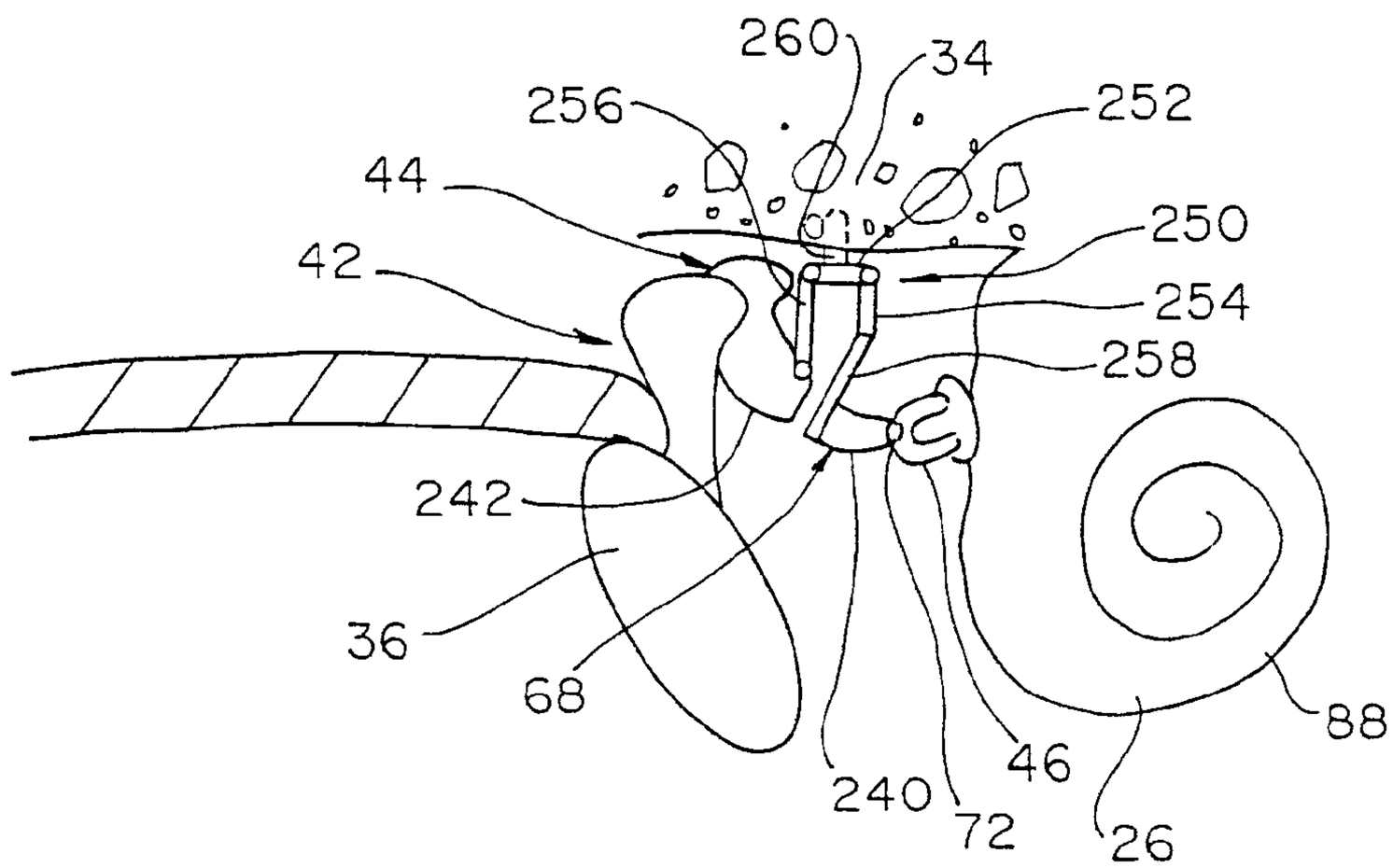
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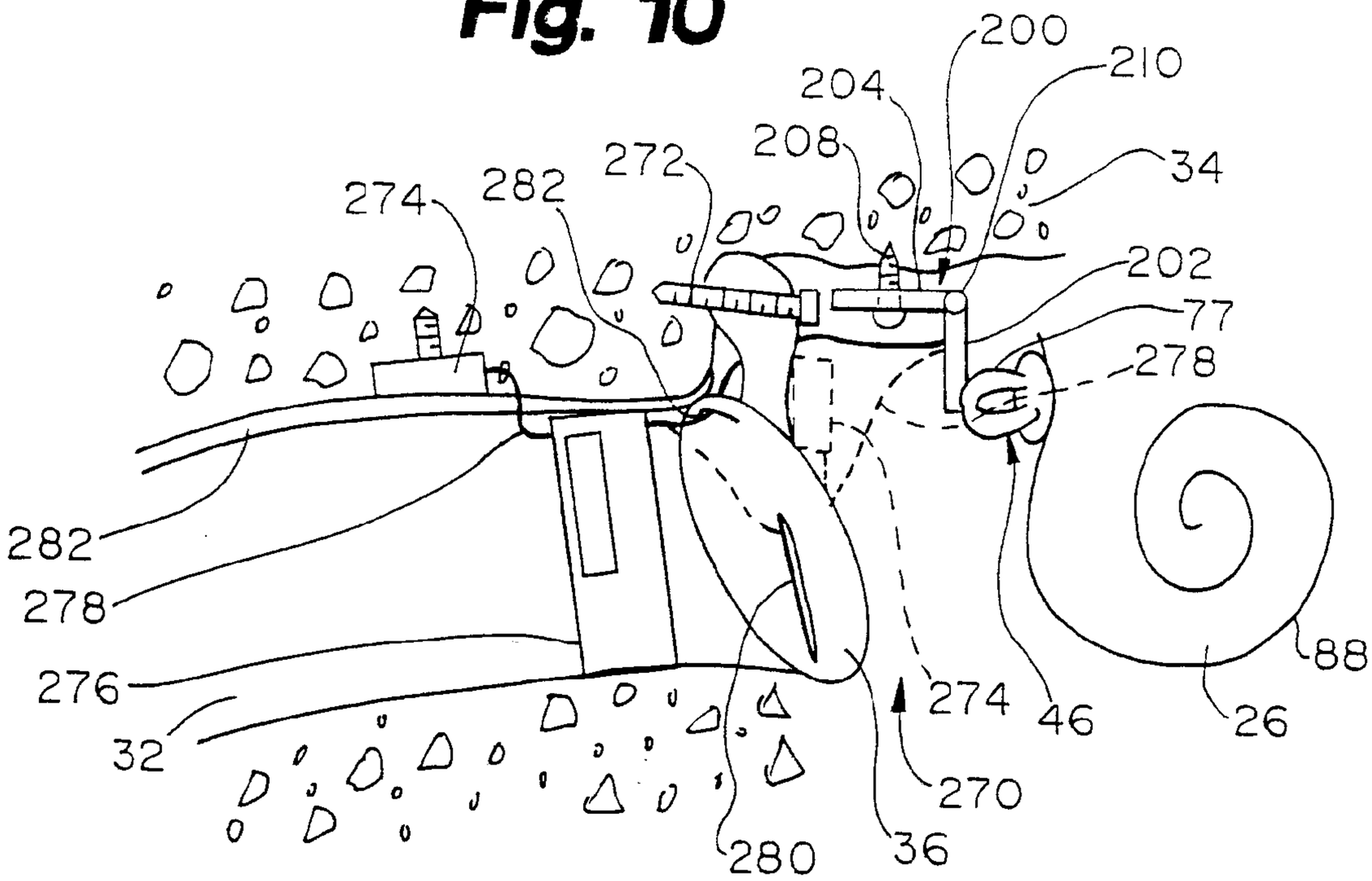



Fig. 11

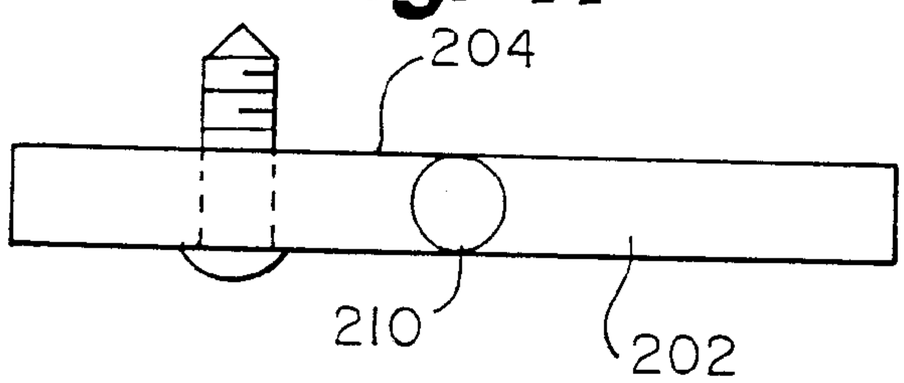
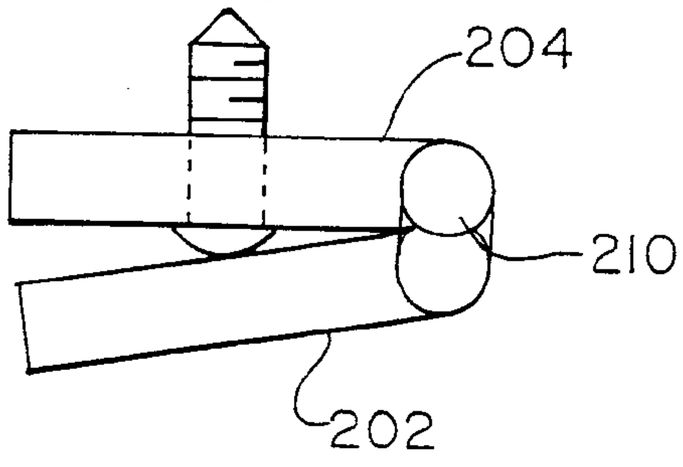



Fig. 12



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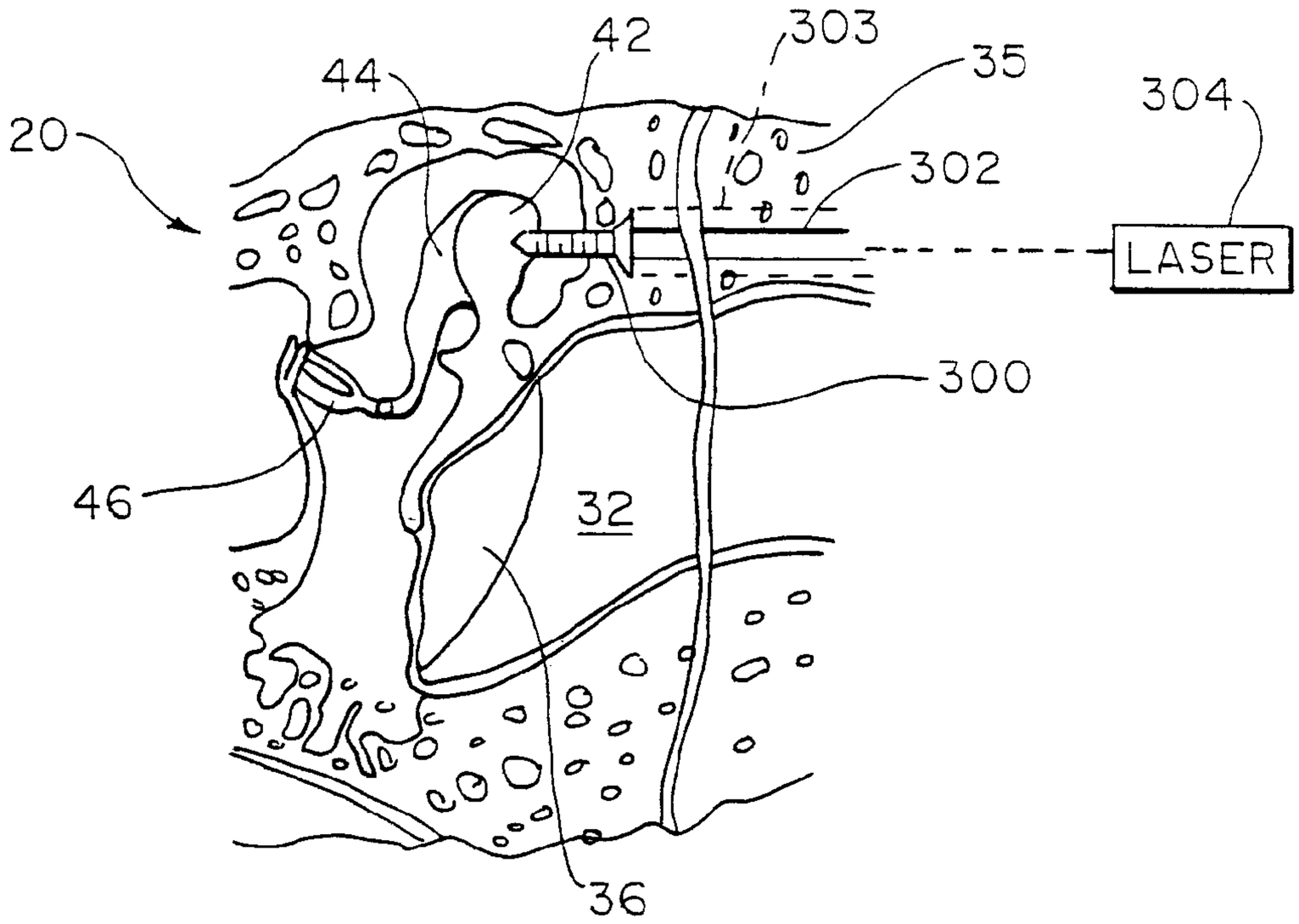
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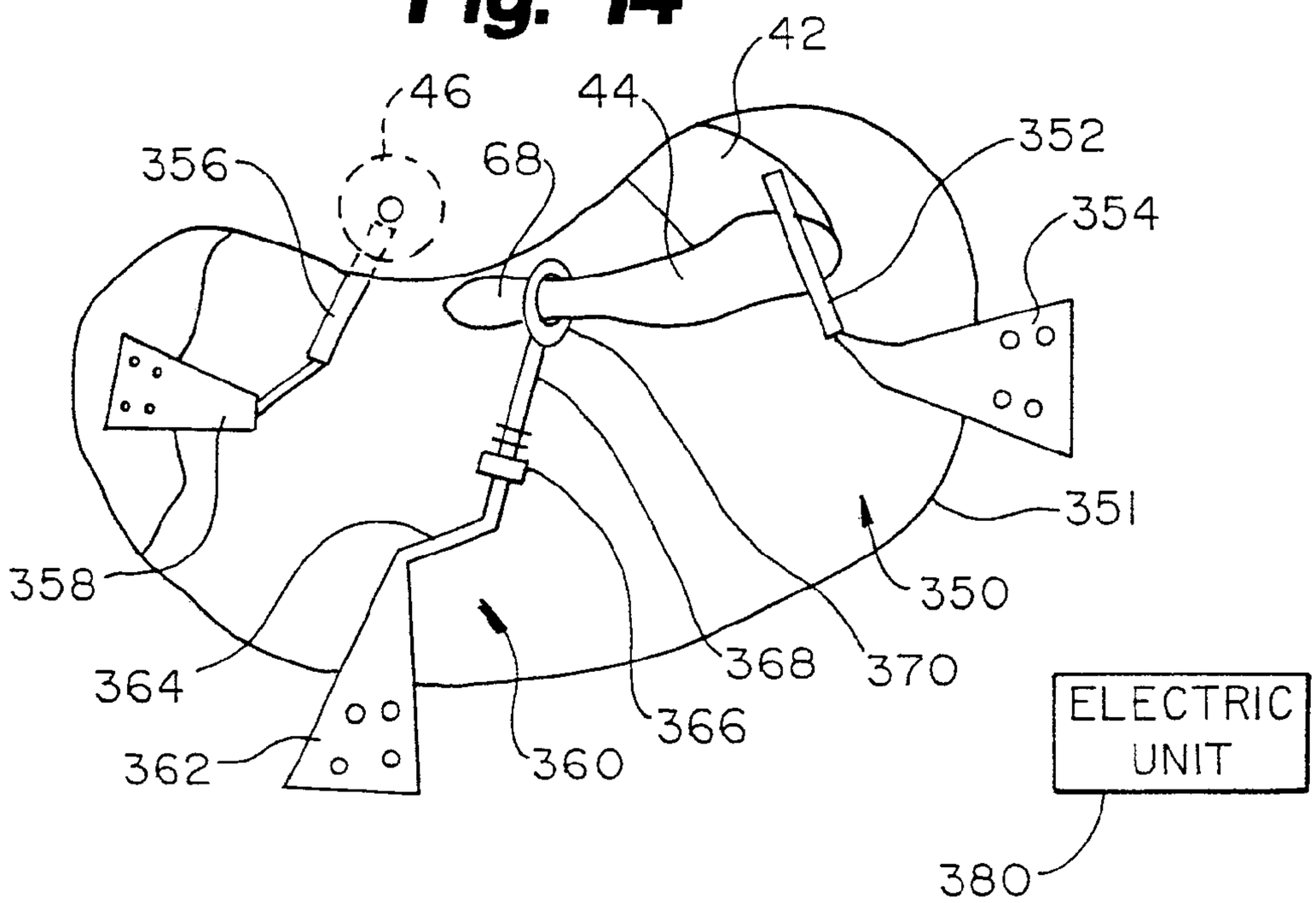
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# METHOD AND APPARATUS FOR REDUCED FEEDBACK IN IMPLANTABLE HEARING ASSISTANCE SYSTEMS

## CROSS-REFERENCE TO RELATED APPLICATION

This application is a divisional of application Ser. No. 09/899,594, filed Jul. 5, 2001, which is in turn a divisional of application Ser. No. 09/327,345, filed Jun. 5, 1999, now U.S. Pat. No. 6,267,731, issued Jul. 31, 2001.

## FIELD OF THE INVENTION

The present invention relates to implantable hearing systems for assisting hearing in hearing impaired persons.

## DESCRIPTION OF RELATED ART

Some implantable hearing assistance systems use a microphone located in or near the ear to convert acoustic sound energy into an electrical signal. The electric signal is amplified, modulated and then directly communicated by a transducer to the inner ear to stimulate the cochlea to assist hearing. Alternatively, the amplified signal is communicated to a transducer for conversion to mechanical acoustic energy for vibratory application to the stapes of the middle ear or the cochlea. The mircrophone can be located externally, subdermally adjacent the ear, or within the external auditory canal. The transducer is commonly connected to a portion of the middle ear, known as the ossicular chain, which includes the malleus, incus and stapes. Vibrations are emitted from the transducer into and through the ossicular chain to the cochlea of the inner ear.

The ossicular chain facilitates forward transmission of mechanical sound vibrations from the tympanic membrane of the external auditory canal to the inner ear. However, the ossicular chain also permits reverse transmission of mechanical sound energy to be transmitted from the transducer of the implantable hearing assistance system, back through the ossicular chain to the tympanic membrane, and into the external auditory canal. This retrograde sound transmission passes out of the external auditory canal and is acoustically fed back to the microphone of the system.

This acoustic feedback limits the maximum gain which the hearing assistance system can apply to the signal received by the microphone. In particular, the feedback created by reverse bone conduction through the ossicular chain has an inverse relationship with usable gain. For example, if one percent of the acoustic vibratory signal emitted by the transducer to the stapes, or other part of the ossicular chain, is fed back through the ossicular chain and into the external auditory canal to the microphone, the gain for the hearing assistance system is limited to roughly 100 or 40 dB. Due to the nature of the hearing losses and the acoustic limitations of these systems, a much higher gain is ideal. Accordingly, reduction or elimination of this feedback is desirable.

Moreover, these hearing assistance systems, which transmit acoustic sound energy onto an ossicular chain with a transducer, are inefficient and consume power rapidly. Inefficiency results from the mechanical force that must be exerted by the transducer against the ossicular chain. This inefficiency causes rapid power consumption, requiring frequent battery changes. Battery changes are, at least, inconvenient for an externally located battery, and at worst, costly and surgically-related for a battery implanted in the middle ear or subdermally.



The importance of restoring hearing to hearing impaired persons demands more optimal solutions in hearing assistance systems. Ideally, an improved hearing assistance system both minimizes power consumption as well as maximizes gain to produce a better acoustic signal for reception into the cochlea and the inner ear.

## SUMMARY OF THE INTENTION

A method and apparatus of the present invention improves hearing for a hearing impaired person by introducing and maintaining a mechanical feedback barrier between a microphone and a transducer of an implantable hearing assistance system. In this method, mechanical sound vibrations impinging on the person's body habitus are received with an electromechanical device (e.g. microphone) disposed at a body habitus sound reception site. The body habitus sound reception site can be located within the external auditory canal, or external of the external auditory canal either subdermally or external of the scalp, or even subdermally along the external auditory canal.

The mechanical sound vibrations are converted with the electromechanical device to an amplified electrical signal. Next, the amplified electrical signal is delivered to the inner ear with a transducer operatively coupled between the electromechanical device and the middle ear or the inner ear.

Finally, a mechanical feedback barrier is introduced and maintained between the sound reception site and the transducer to minimize acoustic feedback therebetween. Preferably, this feedback barrier is established by removing a portion of the hearing impaired person's ossicular chain (e.g. malleus, incus, or stapes) or fixing a portion of the ossicular chain to prevent transmission of sound feedback. In other embodiments, a portion of the ossicular chain is not removed but merely separated so that the procedure can be reversed if desired at a later time.

This method and apparatus of the present invention optimizes hearing improvement by preventing unnecessary mechanical feedback that can occur through the ossicular chain and the external auditory canal. Interrupting the ossicular chain, or otherwise immobilizing the ossicular chain, to prevent this retrograde sound transmission permits significant enhancement of the gain applied to the amplified electrical signal transmitted to the stapes or inner ear. In addition, less mechanical energy is required to transmit the acoustic energy to the interrupted ossicular chain or cochlea than when the ossicular chain remains intact. Accordingly, this method and apparatus reduces power consumption and frequent battery replacement for implantable hearing assistance systems.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a plan view of an auditory system of a human subject.

FIG. **2** is an enlarged plan view of an ossicular chain of the auditory system of FIG. **1**.

FIG. **3** is a sectional view of an auditory system of a human subject incorporating a first embodiment of an implantable hearing system of the present invention.

FIG. **4** is a sectional view of an auditory system of a human subject incorporating a second embodiment of an implantable hearing system of the present invention.

FIG. **5** is a sectional view of an auditory system of a human subject incorporating a third embodiment of an implantable hearing system of the present invention.

FIG. **6** is a sectional view of an auditory system of a human subject incorporating a fourth embodiment of an implantable hearing system of the present invention.

FIG. **7**A is a plan side view of a mounting bracket of the present invention.

FIG. **7**B is a plan top view of a mounting bracket of the present invention.

FIG. **7**C is a plan side view of a modified mounting bracket of the present invention.

FIG. **8** is a sectional view of an auditory system of a human subject incorporating a modification of the embodiment of FIG. **3**.

FIG. **9** is a sectional view of an auditory system of a human subject incorporating another embodiment of an implantable hearing system and method of the present invention.

FIG. **10** a sectional view of an auditory system of a human subject incorporating another embodiment of an implantable hearing system and method of the present invention.

FIG. **11** is a plan side view of a mounting bracket of the present invention manipulated to a pre-insertion position.

FIG. **12** is a plan side view of a mounting bracket of the present invention manipulated to a pre-insertion position.

FIG. **13** is a schematic plan view of a malleus fixation method of the present invention.

FIG. **14** is a schematic view of an incus separation and fixation method of the present invention.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The ear is the auditory organ of the body. As shown in FIG. **1**, ear **20** includes outer ear **22**, middle ear **24**, and inner ear **26**. Outer ear **22**, in turn, includes the pinna **30**, and exterior auditory canal (external acoustic meatus) **32** extending up to and including tympanic membrane **36**. The pinna **30** is the ear flap and is visible on the exterior of the head. The exterior auditory canal extends through temporal bone **34**.

Middle ear **24** begins at the interior terminus of exterior auditory canal **32**, the tympanic membrane **36**. Middle ear **24** includes the interior side of tympanic membrane **36** and ossicular chain **38**. Ossicular chain **38**, in turn, includes malleus (hammer) **42**, incus (anvil) **44**, and stapes (stirrup) **46**.

As best seen from FIG. **2**, malleus **42** includes head **52**, lateral process **54**, anterior process **56**, and manubrium **58**. Malleus **42** attaches to tympanic membrane **36** at manubrium **58**. Incus **44** articulates with malleus **42** at incudomalleolar joint **62** and includes body **64**, short crus **66**, and long crus **68**. Stapes **46** articulates with incus **44** at incudostapedial joint **72** and includes posterior crus **74**, anterior crus **75**, capitulum **76**, and base (foot plate) **79**. Capitulum **76** of stapes **46**, in turn, includes head **77** and neck **78**.

The base **79** of stapes **46** is disposed in and against a portion of the inner ear **26**. Inner ear **26** includes cochlea **88**, vestibule **90**, and semicircular canals **92**. Base **79** of stapes **46** attaches to oval window **98** on vestibule **90**. Round window **102** is present on a more basal portion of vestibule **90**. Oval window **98** and round window **102** are considered a portion of cochlea **88** in this patent application.

Sound waves are directed into exterior auditory canal **32** by outer ear **25**. The frequencies of the sound waves may be slightly modified by the resonant characteristics of exterior auditory canal **32**. These sound waves impinge upon tympanic membrane **36**, thereby producing mechanical tympanic vibrations. The mechanical energy of the tympanic vibrations is communicated to inner ear organs cochlea **88**, vestibule **90**, and semicircular canals **92**, by ossicular chain **38**. Thus, tympanic membrane **36** and ossicular chain **38** transform acoustic energy in exterior auditory canal **32** to mechanical energy at tympanic membrane **36**.

Normally, tympanic vibrations are mechanically conducted through malleus **42**, incus **44**, and stapes **46** to oval window **98**. Vibrations at oval window **98** are conducted into the fluid-filled cochlea **88**. These mechanical vibrations generate fluidic motion, thereby transmitting hydraulic energy within cochlea **88**. Receptor cells in cochlea **88** transmit the fluidic motion into neural impulses, which are transmitted to the brain and perceived as sound. Pressures generated in cochlea **88** by fluidic motions are also accommodated by round window **102**. Round window **102** is a second membrane-covered opening between cochlea **88** and middle ear **24**.

Hearing loss due to damage in cochlea **88** is referred to as sensorineural hearing loss. Hearing loss due to an inability to conduct mechanical vibrations through middle ear **24** is referred to as conductive hearing loss. Some patients have an ossicular chain **38** which lacks resiliency. Ossicular chains with insufficient resiliency are either inefficient or totally fail to transmit mechanical vibrations between tympanic membrane **36** and oval window **98**. As a result, fluidic motion in cochlea **88** is attenuated and receptor cells in cochlea **88** fail to receive adequate mechanical stimulation. Damaged elements of ossicular chain **38** may further interrupt transmission of mechanical vibrations between tympanic membrane **36** and oval window **98**.

A partially implantable hearing assistance system **100** of the present invention for assisting a hearing impaired person is shown generally in FIG. **3** as disposed within ear **20**. It is recognized, however, that system **100** may be a dual system suitable for use with either one or both of a patient's ears. System **100** includes an externally-mounted microphone **102**, an internal amplifier/signal processor **104**, a transducer **106**, and frame assembly **108**. Electrical connection **110** extends from internal signal processor **104** to transducer **106**. A power supply or battery is incorporated into either external microphone **102** or internal signal processor **104**.

External microphone **102** is a conventional microphone or other electromechanical device for converting acoustic sound energy into an electrical signal. In one embodiment external microphone may be a handheld or other similarly configured radio frequency linked system operatively coupled with other components of the hearing assistance system. In another embodiment, external microphone **102** is shaped and sized for removable attachment about the ear **20**, exterior to skin **120**. Internal amplifier **104** includes signal processing circuitry and is either directly electrically connected to microphone **102** through skin **120** or includes a coil transformer for electromagnetically receiving an electrical signal from external microphone **102**. Internal amplifier **104** is preferably attached to the patient's skull below skin **122** subdermally within space **124**. Both microphone **102** and amplifier **104** are miniature electronic modules well known in the art of hearing assistance systems.

Transducer **106** is disposed within middle ear space **24** and secured against a wall of middle ear space **24** or within mastoid cavity **126** against mastoid, bone **34** with frame assembly **108** using one or more fasteners. Finally, transducer **106** is operatively connected to stapes **46**. Electrical connection **110**, which extends from amplifier **104** to transducer **106**, operatively communicatively couples transducer **106** to amplifier **104**.

With system **100**, acoustic sound vibrations impinging on or about outer ear **22** are received by microphone **102** and

converted to an electrical signal and transmitted to amplifier **104**. After amplification and modulation, the electrical signal is communicated to transducer **106** via electrical connection **110**. In response to the electrical signal, transducer **106** produces an acoustic vibratory signal that is applied to stapes **46** and ultimately, cochlea **88** via oval window **98**. Microphone **102**, amplifier **104**, and transducer **106** and their communication with each other may be of a type generally known to those skilled in the art, although improved transducer means are contemplated within the scope of this invention to facilitate improved implant procedures, to minimize invasiveness, and to improve the reliability of the transducer.

Finally, system **100** and the method of the present invention includes introducing and maintaining a mechanical feedback barrier to prevent mechanical or acoustic feedback from transducer **106** to microphone **102**. This feedback barrier is preferably implemented by interrupting ossicular chain **38**. However, freezing movement of ossicular chain **38** or otherwise isolating microphone **102** and transducer **106** from mechanical/acoustic feedback through ossicular chain **38** can also provide the necessary barrier. In addition, the feedback barrier can be accomplished through various sound dampening and sound isolation materials and/or techniques placed appropriately about, or between, one or more portions of the ossicular chain.

As shown in FIG. **3**, ossicular chain **38** including malleus **42**, incus **44**, and stapes **46** has been interrupted by disconnecting incus **44** from stapes **46**. This interruption creates a barrier to prevent mechanical feedback of acoustic sound energy from transducer **106** through ossicular chain **38** and external auditory canal **32**, to microphone **102**. Of course, the disarticulation of ossicular chain **38** could occur any place between tympanic membrane **36** (umbo) and transducer **106**.

In addition, the transducer **106** can be directly coupled to oval window **98** or round window **102** of cochlea **88** by prior removal of stapes **46**. In that embodiment, removal of stapes **46** acts to disarticulate the ossicular chain **38** to prevent feedback and permits malleus **42** and incus **44** to remain in place. Maintaining a connection of at least malleus **42** (and optionally incus **44**) to tympanic membrane **36** may also aid in preventing damage from acoustical trauma, since maintaining malleus **42** further enables the natural musculoskeletal defense mechanisms to protect against acoustical trauma.

While removal of ossicular chain **38** has taken place in some prior methods and systems, such removal typically occurs to solve middle ear conduction-type hearing loss problems, or to remove diseased tissue and ossicular bones. Sensorineurally impaired patients have hearing impairments not caused by dysfunction of the middle ear conduction chain, i.e. ossicular chain **38**. Accordingly, sensorineural impairments do not dictate removal of ossicular chain **38**. In fact, some in the art believe it unethical, or at least inappropriate, to remove a healthy ossicular chain to remedy a hearing impairment Accordingly, removing or freezing movement of a portion of ossicular chain **38**, or otherwise isolating ossicular chain **38** from an implantable middle ear system, such as system **100**, in sensorineurally impaired patients is a unique and counter-intuitive solution to reduce acoustic feedback and improve the gain of the hearing assistance system.

While maintaining ossicular chain **38** intact (in order to preserve a healthy ossicular chain **38** despite a hearing impairment) may appear to be less intrusive, a method of the present invention recognizes that unconditionally maintaining the chain can dramatically reduce the gain achieved by the implantable middle ear hearing assistance system due to the feedback phenomenon described above. In this manner, the choice to maintain ossicular chain **38** can actually impede improving hearing in hearing impaired patients, particularly those with sensorineural impairment However, in certain circumstances according to each patient's middle ear morphology, this invention may not be limited to the class of patients which only includes those suffering from sensorineural impairment. Accordingly, the method of the present invention interrupts ossicular chain **38** to prevent feedback, particularly for sensorineurally impaired patients.

Another hearing assistance system **130** of the present invention is shown in FIG. **4**. System **130** includes electromechanical device **132** (e.g. microphone), amplifier/signal processor **134**, transducer **136**, and frame assembly **138** with electrical connections **140** and **142**. Microphone **132** has features and attributes similar to microphone **102**, except for its implantation below skin **120** subdermally. Signal processor **134** includes an amplifier and signal processing characteristics for amplifying and filtering an electrical signal from microphone **132**. A battery may be incorporated with signal processor **134** as shown, or optionally incorporated externally adjacent ear **120**, or incorporated with microphone **132**. Transducer **136** has features and attributes similar to transducer **106** and is, likewise, connected to stapes **46** via head **77**. As in the embodiment of FIG. **3**, transducer **136** can alternatively be operatively coupled to round window **102** or oval window **98** of cochlea **88**. Signal processor **134** is secured to the mastoid bone **34** within cavity **126**. Electrical connection **140** extends between microphone **132** and processor **134** while electrical connection **142** extends between, and electrically couples processor **134** and transducer **136**. As shown in FIG. **4**, incus **44** was removed from ossicular chain **38** to introduce and maintain a feedback barrier against transmission of mechanical sound energy through ossicular chain **38** from transducer **136** to external auditory canal **32**, and ultimately, microphone **132**. Of course, as earlier noted, other portions can be removed from ossicular chain **38** in place of removing incus **44** to effect the disarticulation and interruption of ossicular chain **38** to prevent acoustic feedback.

This method and system **132** enjoys advantages and features similar to system **100** as a result of the introduction of an acoustic feedback barrier between microphone **132** and transducer **136**.

Another partially implantable hearing system **150** of the present invention is shown in FIG. **5**. System **150** includes a single unit implantable device **152**, including a microphone, amplifier, and battery. System **150** further includes transducer **156**, frame assembly **158**, and electrical connection **160**. Device **152** is removably secured within the auditory canal, for example in external auditory canal **32**, while transducer **156** is supported within the middle ear cavity **24** by connection assembly **158** secured against mastoid bone **34** within cavity **126**. As before, transducer **156** is secured to head **77** of stapes **46** or, alternatively, secured to the oval or round windows of cochlea **88** in the absence of stapes **46**. As in the other systems **100** and **130**, disarticulation of the ossicular chain **38** creates a feedback barrier to prevent a retrograde transmission of sound energy from the transducer **136** through the external auditory canal **32** to microphone of device **152**. As shown, ossicular chain **38** has been interrupted, or disarticulated, by separating incus **44** from stapes **46**. However, disarticulation could take other forms, including removal of incus **44**, removal of

malleus **42** or removal of stapes **46**, or any combination thereof. Moreover, as discussed further below in connection with FIG. **9**, disarticulation can include cutting or removing a portion of the incus to interrupt the ossicular chain, as well as other techniques.

In another embodiment of the present invention shown in FIG. **6**, a hearing assistance system **170** includes features and attributes similar to system **100** shown in FIG. **3** by having an external microphone or electromechanical device **172** and an internal amplifier **174**. However, in system **170**, an electrical stimulator, such as a piezoelectric accelerometer **176** is mounted within mastoid cavity **126**, as shown in phantom, or on the head of malleus **142**. Electrical stimulator **176** includes leads **178** for electrical connection to various portions of cochlea **88** for electrical stimulation thereof to produce neural impulses corresponding to the acoustic sound received by microphone **172**, as known in the art. Electrical connection **180** operatively couples amplifier **174** to stimulator **176**. Finally, alternatively to electrical stimulator **176**, mechanical stimulator **180** can be operatively coupled to round or oval window of cochlea **88**. As shown in FIG. **6**, as in the other of the present invention systems **100**, **130**, and **150** a feedback barrier is introduced between microphone **172** and stimulator **176** or **180** by disarticulation of ossicular chain **38**. Disarticulation of the ossicular chain is accomplished by removal of the stapes **46** or separation of ossicular chain **38** elements (without their removal). Of course, the other microphone and amplifier combinations as shown in FIGS. **4** and **5** can be implemented with an electrical stimulator, such as stimulator **176** (or the alternative mechanical stimulator **180**).

Implementing the method of the present invention in the embodiment of FIG. **6** insures no inadvertent acoustic/mechanical feedback occurs through ossicular chain **38** to microphone **172** from stimulator **176**, **180** or from cochlea oval window **98** even though direct stimulation of cochlea **88** occurs apart from ossicular chain **38**.

FIGS. **3–5** each show a mounting bracket (**108**, **138**, **158**) for placing a transducer in contact with an auditory element of the stapes. While brackets known in the art can be used, the method and systems of the present invention may also use a bracket of the type similar to that shown in FIGS. **7A–7C**. FIGS. **7A**, **7B**, and **7C** show a bracket system **200** having a transducer **202** attached to the single bracket support **204**. The single bracket support **204** includes an opening **206**. A bone screw **208** or similar attaching means passes through the oblong opening **206** and allows for independent adjustment of the distance between the support mounting screw **208**, which is typically a bone screw, and the transducer **202**. Such adjustment allows flexibility in that the single bracket support can be mounted with respect to different auditory elements, such as the malleus **42** and the stapes **46**, respectively, in a patient population having varying anatomical features within the middle ear **24**.

The shape of single bracket support **204** in this embodiment is more or less a flat plate. The transducer **202** is coupled to the flat plate either adhesively, mechanically or otherwise, to produce a single component. It should be noted that other configurations are possible, depending on patient anatomy and other factors. A generally L-shaped bracket, a rectangular-shaped bracket, or any other shaped bracket that facilitates mounting of transducer **202** can be used in place of the single bracket support **204**. The bone screw **208** couples the single bracket support **204** to the mastoid bone **34**. Other types of fastening techniques can also be used. For example, single bracket support **204** can be shaped with a flange that could be attached to the mastoid bone **34**. The single bracket support **204** can be moved linearly and rotated with respect to the bone screw **200** to position the transducer **202** in a selected position with respect to one of the elements of the middle ear.

FIG. **7C** shows an embodiment having a universal connector **210** placed between the transducer **202** and the single bracket support **204**. The universal connector **210** may also be placed between the two portions of the single bracket support **204**. The universal connector **210**, such as a ball and socket joint, allows further adjustability and 360-degree movement to position the transducer **202** against respective auditory elements **42** and **46**.

As shown in later FIGS. **8** and **9**, bracket system **200** can include multiple bracket supports **204** each having a universal connector **210** for adjustability. In addition, the bracket systems **200** can include multiple slots such as slot **206**, laterally spaced from each other and having different lengths, to permit flexibility in selecting the length at which bracket support **204** extends outwardly from its point of attachment to the mastoid bone or middle ear structure.

As shown in prior FIGS. **3–5**, a fastener, such as bone screw **208** is attached to the mastoid bone **34** to secure the bracket **200** within middle ear space **24** and transducer **202** adjustably in contact with stapes **46**. Of course, bracket **202** also permits transducer **202** to be adjustably in contact with the malleus **42** via universal joint **210**. The various transducer and mounting means of the invention facilitate a trans-canal implant procedure by which portions of the device of the invention are implanted, in one embodiment, through the auditory canal and the tympanic membrane into the middle ear.

Another system **220** and method of the present invention is shown in FIG. **8**. System **220** includes system **100** as shown in FIG. **3** and further includes securing incus **44** into a fixed position within the middle ear. Accordingly, system **200** further includes additional bracket support **221** (with universal joint **222**) affixed to long process **68** of incus **44**. Bracket **221** secures incus in a position separated from stapes **46** to prevent retrograde transmission of sound along the ossicular chain. Bracket **221** could also be implemented to secure incus **44**, malleus **42**, or stapes **46** in a configuration, where none of the auditory elements (incus, malleus, stapes) have been removed nor separated from each other, to effectively freeze the ossicular chain preventing transmission of sound along the chain. In this latter configuration, incus **44** remains connected to stapes **46** (as shown in FIG. **1**) and bracket **221** is connected to malleus **42**, incus **44**, or stapes **46** with sufficient tension to freeze motion of the ossicular chain to establish a mechanical feedback barrier.

Another method and system of the present invention for maintaining a mechanical barrier against feedback is illustrated in FIG. **9**. As shown in FIG. **9**, malleus **42**, incus **44** and stapes all remain within middle ear space **24**. However, incus **44** includes long process **68**, which has been surgically cut (e.g. by laser or other means) into first portion **240** and second portion **242**. As further shown in FIG. **9**, system **250** of the present invention includes bracket support frame **252**, bracket extensions **254** and **256**, transducer **258** and fastener **260**.

Implementing bracket system **250** in a method of the present invention includes interrupting the ossicular chain to prevent feedback by cutting incus **44** into two separate portions **240** and **242**. This method can be used in conjunction with the hearing systems of FIGS. **2–5** and **8** to establish a mechanical feedback barrier wherein cutting incus **44** is

substituted for: (1) removing incus **44**; (2) separating incus **44** from the stapes **46** or malleus **42**; or (3) any other method of interrupting the ossicular chain, such as freezing or fixing the position of the ossicular chain without cutting or separating elements of the chain.

Next, the method includes mounting bracket system **250** against mastoid bone **34** with fastener **260** and manipulating bracket extension **254** to place transducer **258** in contact with portion **240** of long process **68** of incus **44**. Next, transducer **258** is operatively secured or positioned against the exposed end of portion **240** with an adhesive or other known fastening means. The cut through long process **68** of incus **44** is made so that a separation of at least about 2 to 3 millimeters is maintained between the ends of incus portions **242** and **240**, accounting for a transducer thickness of about 0.5 millimeters mounted on the end of incus portion **240**. This separation distance prevents mucosal growth or bone re-growth that could otherwise act to rejoin incus portions **240** and **242**.

With this configuration, transducer **258** can receive an electrical signal and transmit to incus portion **240** a sound vibration signal for delivery to inner ear **26** via stapes **46**. Transducer **258** receives its signal from an electromechanical device (e.g, microphone) and/or amplifier disposed in one of the configurations shown in FIGS. **2–5**, **8**, and **10**.

This method preserves incudostapedial joint **72** so that natural transmission occurs from incus **44** to stapes **46** and so that in the event the procedure needs to be reversed, incudostapedial joint need not be re-created but rather incus portions **240** and **242** can simply be fused together. This method also preserves the lenticular process on stapes **46**. In short, this method permits interruption of the ossicular chain in a minimally invasive and reversible manner, while enhancing hearing assistance.

While feedback can be prevented with portion **240** of incus **44** being merely separated from portion **242**, it is preferred, as shown, to optionally further secure incus portion **242** into a fixed position with bracket extension **256** to insure incus portion **242** remains separated from portion **240** at an adequate minimum separation distance (e.g. about 2–3 millimeters) to prevent tissue reconnection or inadvertent contact between incus portions **240** and **242**.

As shown in FIG. **10**, a human auditory canal is depicted with system **270** and a method of the present invention incorporated therein. System **270** for implementing a method of the present invention includes bracket system **200** (see FIGS. 7A–7C) having transducer **202**, bracket support **204**, positioning slot **206** (not seen in FIG. **10**), fastener **208**, and universal connector **210**. System **270** further includes malleus fastener **272**, microphone **274**, amplifier/electronics unit **276**, lead wires **278**. Finally, the method includes formation of slit or hole **280** in tympanic membrane **36**.

First, in this method, microphone **274** preferably is located along external auditory canal **24** in contact with the canal wall **282**. This configuration takes advantage of the known sound filtering and amplification characteristics and localization effects of the outer ear **22** (including the structure shown in FIG. **1** extending from the pinna **30** to the tympanic membrane **36**) of the human auditory system. This microphone location can be implemented to substitute for any of the microphone locations of the systems shown and described relative to FIGS. **2–6** and **8–9**. Microphone **274** is preferably a directional microphone which receives sound transmission traveling inwardly through the external auditory canal **32** while excluding sound transmission traveling outwardly through the external auditory canal **32**.

In addition, as will be further described later, microphone **274** can be located within middle ear space **24** behind tympanic membrane **36**, preferably on malleus **42** as shown in phantom in FIG. **10**. When microphone **274** is an acoustic microphone, this placement also takes advantage of the sound filtering, amplification, and localization effects of outer ear **30**.

Second, amplifier/electronics unit **276** is placed in external auditory canal **32** or another location available (e.g. pectoral, or outside skull) to avoid a mastoidectomy procedure. Placement of amplifier/electronics unit at a pectoral location permits the use of long life batteries having a size normally unsuitable for middle ear implantation and/or permits easier battery replacement Amplifier **276** is electrically connected to microphone **274** with lead wires **278** (shown in phantom for microphone placement on malleus **42**). Lead wires **278** pass through slit **282** (or slit **280**) of tympanic membrane **36** for connection to transducer **202**.

The following method of insertion is used for implanting at least transducer **202**, electromechanical device **274** (in phantom in FIG. **10**) or any other component hearing assistance system **270** within middle ear space **24**.

First, transducer **202** is affixed to a mounting bracket prior to insertion in the middle ear. The mounting bracket system **200** preferably includes a universal joint **210** disposed between a first elongate portion (support **204**) and a second elongate portion (transducer **202**). The second portion **202** commonly includes both a support and the transducer affixed together.

Prior to insertion in the middle ear, first portion **204** and second portion **202** of mounting bracket system **200** are manipulated to be aligned in an elongate configuration generally parallel along a single axis. The configuration can include either arranging first portion **204** and second portion **202** of the mounting bracket **200** in a side-by-side relationship generally parallel to each other as shown in FIG. **11**, or as shown in FIG. **12**, arranging first portion **204** and second portion **202** of mounting bracket **200** in an end-to-end relationship (aligned generally parallel along a single axis). In general, first portion **204** and second portion **202** need not be generally parallel but can be in any configuration (e.g. 45 or 90 angle) that facilitates insertion of mounting bracket **200** into the middle ear space **24** through tympanic membrane **36**.

Next, using surgical techniques known to those skilled in the art, a low profile entry slit or hole **280** is created in tympanic membrane **36**. With the mounting bracket system **200** and transducer in one of the above low profile configurations (see, e.g., FIG. **11**), mounting bracket **200** is inserted into and through slit **280** in tympanic membrane **36**. After first portion **204** and second portion **202** of mounting bracket **200** are reconfigured into an operative in-use configuration (e.g. 30, 60 or 90 angles), bracket **200** is then mounted against a wall of the middle ear space or against mastoid bone **34** as shown. In a system, such as that shown in FIG. **10** (microphone **274** and electronics unit **276** external to middle ear), middle ear implantation of transducer **202** via tympanic membrane **36** avoids a mastoidectomy. After insertion of the transducer **202** through slit **280**, tympanic membrane **36** will heal appropriately.

This method permits insertion of a device such a bracket/transducer combination into the middle ear without a mastoidectomy where the bracket/transducer can be deployed in the middle ear space in a configuration different than the configuration used for insertion through tympanic membrane.

Of course, in the embodiment where microphone **274** is mounted behind tympanic membrane **36** on malleus **42** (shown in phantom), microphone **274** can be inserted through tympanic membrane **26** without a mounting bracket **200**. Instead, microphone **274** may include adhesive means for mounting to malleus **42** or other fastening system.

Moreover, the method of insertion/implantation through tympanic membrane **36** according the present invention is not limited to the use of bracket **200**. Accordingly, any transducer or component of a hearing assistance system can be inserted through tympanic membrane **36** without a bracket like bracket system **200** for implantation in middle ear **24**. For example, the other systems shown in FIGS. **2–6, 8–9** that have at least a transducer or electromechanical device or component of a hearing assistance system can be implanted with the just described method of insertion instead of using a mastoidectomy.

In addition, insertion through tympanic membrane **36** can optionally be combined with other features of the present invention such as securing an auditory element into a fixed position. Accordingly, as shown in FIG. **10**, malleus **42** is secured in a fixed position by fastener **272** to prevent transmission of feedback sound energy along the ossicular chain. Of course, other fastening means such as brackets, like bracket system **200**, sutures, bone cement and adhesives can be used.

In addition, the cochlea stimulator embodiments of FIG. **6** can be modified so that microphone **172** is replaced with a microphone located behind the tympanic membrane **36** within middle ear space **24**, such at microphone **274** ( shown in phantom in FIG. **10**) attached to malleus **42**.

The method and system of the present invention improves hearing assistance for the hearing impaired in implantable hearing systems using a microphone by neutralizing acoustic feedback through the ossicular chain and external auditory canal. The method can be employed in virtually all combinations of implantable systems having microphones located externally, subdermally, or within or along the external auditory canal. Elimination of acoustic feedback through the ossicular chain produces better gain in these systems, and reduces power consumption since less mechanical force is required to transmit acoustic signals into the inner ear (via stapes or not) with an interrupted ossicular chain. Moreover, the methods of the present invention are minimally invasive procedures using tympanic insertion of a transducer or mounting bracket and/or reversible procedures using separation of the ossicular chain without removal of any auditory elements or without dismembering any joints such as the incudostapedial joint.

A further method and system of ossicular chain fixation of the present invention for reducing mechanical feedback is shown in FIG. **13**. FIG. **13** shows auditory system **20** including external auditory canal **32**, bone **35** (e.g. temporal bone), tympanic membrane **36**, malleus **42**, incus **44**, and stapes **46**. In this method, hole **302** is drilled through bone **35** (preferably temporal bone near the zygomatic root) until malleus **42** is visualized. Next, laser **304** is used to cut a hole in the head of malleus **42** for receiving fastener **300** (e.g., screw, rivet, pin, etc.). Fastener **300** is then inserted into and through hole **300** and securely fixed into head of malleus **42** with a portion (e.g. Head) of fastener **30** remaining within bone **35**. This arrangement securely fixes head of malleus **42** to bone **35**, thereby restraining movement of malleus **42** and thereby reducing and/or preventing mechanical feedback through ossicular chain according the method of the present invention previously described. As seen in FIG. **13**, in this embodiment, the elements of the ossicular chain are not separated from each other although separation of one or more elements of the ossicular chain may optionally be done in combination with fixation of malleus by fastener **300**.

In addition, other methods of access to malleus **42** for fixing fastener **300** thereon can be used such as a mastoidectomy, or access through a wall of the external auditory canal, or other methods available to those skilled in the art. FIG. **13** also shows hole **303** in phantom to represent the possible need for a wider hole to accommodate a head of fastener **300** as necessary.

Finally, in another embodiment of a method of fixation and separation of the ossicular chain of the present invention, a combined fixation and separation system **350** operates to separate incus **44** from stapes **46** (e.g. at incudostapedial joint) and securely fix incus **44** to restrain its movement. As shown in FIG. **14**, system **350** is implemented with malleus **42**, incus **44**, and stapes **46**, all of which are visible (except stapes **46**) through an access hole **351** provided by a partial or whole mastoidectomy or other surgical techniques for gaining access to the ossicular chain. System **350** includes sensor **352** with accompanying support bracket **354**, stapes driver **356** with accompanying support bracket **358**, and incus fixator **360**. Fixator **360** includes supporting bracket **362**, extension support **364** having a selectively variable position, fastener **366**, fixator arm **368** and ring **370**.

In use, stapes **46** is separated from incus **44** as shown. Sensor **352** and driver **356** are operatively coupled to malleus **42** and stapes **46**, respectively, using known techniques and/or supporting brackets **354** and **358**. Sensor **352** and driver **356** are operatively coupled to each other and/or electronics unit **380** via electrical wires, and can omit or include further combinations of intervening signal processing, amplification, filtering and gain compression components as necessary.

Ring **370** of incus fixator **360** is maneuvered about long process **68** of incus **44**, operating as a lasso to slip over the free end of incus **44** to effectively grasp incus **44**, creating an operative coupling of fixator arm **368** to incus **44**. Supporting bracket **362**, selectively variable position extension arm **364**, and fastener **366** are manipulated into a selected fixed position to maintain incus **44** in a fixed position separated from stapes **46**. This arrangement prevents mechanical feedback through the ossicular chain in accordance with the previously described methods of the present invention.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit or scope of the present invention. However, what is disclosed includes as a minimum the following various concepts. A method and apparatus assists a hearing impaired person by introducing and maintaining a mechanical feedback barrier between a microphone and a transducer of an implantable hearing assistance system. In this method, mechanical sound vibrations impinging on the person's body habitus are received with an electromechanical device (e.g. microphone) disposed at a body habitus sound reception site. The body habitus sound reception site can be located within the external auditory canal, or external of the external auditory canal either subdermally or external of the scalp. The mechanical sound vibrations are converted with the electromechanical device to an amplified electrical signal. Next, the amplified electrical signal is delivered to the inner ear with

a transducer operatively coupled between the electromechanical device and the middle ear or the inner ear. Finally, a mechanical feedback barrier is introduced and maintained between the sound reception site and the transducer to minimize acoustic feedback therebetween. Preferably, this feedback barrier is established by removing, separating, or fixing, or combinations thereof, a portion of the hearing impaired person's ossicular chain (e.g malleus, incus, or stapes). In another embodiment, a method and apparatus assists a hearing impaired person by introducing and maintaining a mechanical feedback barrier between a microphone and a transducer of an implantable hearing assistance system. In this method, mechanical sound vibrations impinging on the person's body habitus are received with an electromechanical device (e.g. microphone) disposed at a body habitus sound reception site. The body habitus sound reception site can be located within the external auditory canal, or external of the external auditory canal either subdermally or external of the scalp. The mechanical sound vibrations are converted with the electromechanical device to an amplified electrical signal. Next, the amplified electrical signal is delivered to the inner ear with a transducer operatively coupled between the electromechanical device and the middle ear or the inner ear. Finally, a mechanical feedback barrier is introduced and maintained between the sound reception site and the transducer to minimize acoustic feedback therebetween. Preferably, this feedback barrier is established by removing, separating, or fixing, or combinations thereof, a portion of the hearing impaired person's ossicular chain (e.g., malleus, incus, or stapes). In another embodiment, a method and apparatus assists a hearing impaired person by introducing and maintaining a mechanical feedback barrier between a microphone and a transducer of an implantable hearing assistance system. In this method, mechanical sound vibrations impinging on the person's body habitus are received with an electromechanical device (e.g. microphone) disposed at a body habitus sound reception site. The body habitus sound reception site can be located within the external auditory canal, or external of the external auditory canal either subdermally or external of the scalp. The mechanical sound vibrations are converted with the electromechanical device to an amplified electrical signal. Next, the amplified electrical signal is delivered to the inner ear with a transducer operatively coupled between the electromechanical device and the middle ear or the inner ear. Finally, a mechanical feedback barrier is introduced and maintained between the sound reception site and the transducer to minimize acoustic feedback therebetween. Preferably, this feedback barrier is established by removing, separating or fixing, or combinations thereof, a portion of the hearing impaired person's ossicular chain (e.g., malleus, incus, or stapes).

What is claimed is:

**1**. A method for assisting hearing for a sensorineurally hearing impaired person comprising:

receiving sound vibrations impinging on the person's body habitus with an electromechanical device disposed at a body habitus sound reception site and converting the sound vibration with the electromechanical device to an amplified electrical signal, wherein the electromechanical device is a microphone located subdermally along and in contact with the external auditory canal;

delivering the amplified electrical signal to the inner ear with a transducer means operatively coupled between the electromechanical device and the inner ear;

prior to the receiving and delivering steps, inserting at least one of the electromechanical device and the transducer through the tympanic membrane for implantation in the middle ear.

**2**. The method of claim **1**, wherein the maintaining step further comprises:

maintaining a mechanical feedback barrier between the sound reception site and the inner ear to minimize feedback therebetween during the receiving and delivering steps.

**3**. The method of claim **1**, wherein the inserting step further comprises:

prior to insertion in the middle ear, affixing at least one of the electromechanical device and the transducer to a mounting bracket.

**4**. The method of claim **3**, wherein the mounting bracket includes a universal joint for adjustable mounting the electromechanical device and the transducer in contact with an auditory element of the ossicular chain.

**5**. The method of claim **3**, wherein the inserting step further comprises:

prior to insertion in the middle ear, manipulating a first and a second portion of the mounting bracket to be aligned in an elongate configuration generally parallel along a single axis.

**6**. The method of claim **5**, wherein the manipulating step further comprises:

arranging the first and second portion of the mounting bracket alongside each other.

**7**. The method of claim **5**, wherein the manipulating step further comprises:

arranging the first and second portion of the mounting bracket in an end-to-end relationship.

**8**. A method for assisting hearing for a sensorineurally hearing impaired person comprising:

receiving sound vibrations impinging on the person's body habitus with an electromechanical device disposed at a body habitus sound rejection site and converting the sound vibration with the electromechanical device to an amplified electrical signal;

delivering the amplified electrical signal to the inner ear with transducer means operatively coupled between the electromechanical device and the inner ear;

prior to receiving and delivering steps, inserting at least one of the electromechanical device and the transducer through the tympanic membrane for implantation in the middle ear by affixing at least one of the electromechanical device and the transducer to a mounting bracket and manipulating a first and a second portion of the mounting bracket to be aligned in an elongate configuration generally parallel along a single axis.

**9**. The method of claim **8**, wherein the mounting bracket includes a universal joint for adjustable mounting the electromechanical device and the transducer in contact with an auditory element of the ossicular chain.

**10**. The method of claim **8**, wherein the manipulating step further comprises:

arranging the first and second portion of the mounting bracket alongside each other.

**11**. The method of claim **8**, wherein the manipulating step further comprises:

arranging the first and second portion of the mounting bracket in an end-to-end relationship.

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